Consultation Report

Topic details

Title of policy or policy statement:	Clinical Commissioning Policy Proposition: Vedolizumab for refractory ulcerative colitis in pre-pubescent children
Programme of Care:	Women and children
Clinical Reference Group:	Paediatric medicine
URN:	1862

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition. The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 2nd October until 1st November 2019. There were no responses to the public consultation.

2. Background

Ulcerative colitis (UC) is a long-term condition that mainly affects the bowel. Some people may develop symptoms that affect other body parts as well. The cause of UC is unknown and it can develop at any age, although peak incidence is between the ages of 15 and 25 years. Symptoms of active disease can include bloody diarrhoea, an urgent need to defaecate (poo) and abdominal (tummy) pain. UC is a lifelong disease that is associated with significant impact on patients' lives. It can also affect a person's social and mental wellbeing, particularly if poorly controlled.

Treatment is largely to relieve symptoms rather than cure. For mild disease, two types of therapies are generally used: aminosalicylates or steroids. For moderate to severe disease, add on therapy with stronger immunosuppressive medications such as tacrolimus or ciclosporin are used. Infliximab, a tumour necrosis factor (TNF) alpha inhibitor can be used in severe, active UC. For children who have failed all the treatment as stated above, there is no alternative licensed therapy. These patients may be dependent on long-term steroids or require surgical interventions.

Vedolizumab is a biological medicine given through intravenous infusions. It targets a protein found on the surface of certain white blood cells involved in causing inflammation in the gut. It is licensed for the treatment of adults with moderately to severely active UC as the fourth line treatment. Vedolizumab is not licensed for this indication in pre-pubescent children.

This policy proposition is 'not for routine commissioning', as there is considered to be not enough evidence to make the treatment available at this time. It has been subject to stakeholder testing and public consultation in line with the standard Methods.

3. Publication of consultation

The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 2nd October to 1st November 2019. No responses were received during this time; therefore, no changes to the policy proposition have been made.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to be made to this document, and why?

4. Results of consultation

All stakeholders (including CRG members and registered stakeholders) were notified when the draft policy proposition went out to public consultation. Despite this, there were no responses.

5. How have consultation responses been considered?

Not applicable, as no responses received.

6. Has anything been changed in the policy as a result of the consultation?

Not applicable.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposal?

No.